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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/409,792	09/30/1999	MARTIN P. FOLEY	6298/308	5860

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EXAMINER

LEWIS, AARON J

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5P

<b>Office Action Summary</b>	Application No. 09/409,792	Applicant(s) FOLEY ET AL.	
	Examiner AARON J. LEWIS	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03/07/2005 (RCE).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-52 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-42 is/are allowed.
- 6) ☒ Claim(s) 31, 32, 34, 35 and 43-52 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 31,32,35 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker ('671).

As to claim 31, Baker discloses a mask for inhalation of medication (col.2, lines 11-14) comprising: a front portion having an inlet (20) adapted for connection to a source (22) for providing an aerosol medication, wherein said mask has minimal dead space inside (figs.1-3) yet provides efficient inhalation and exhalation flow paths that purge said mask of exhaled air; a side wall expanding outwardly from said front portion to a rear portion (see portion that engages a wearer's face in figs.1-3) adapted to fit sealingly (col.2, lines 57-59) on a human face; a wall located adjacent said front portion, and a valve (26) integrally formed (col.2, lines 20-24) in an opening in said wall, said wall and said valve (26) form a single piece of material (col.2, lines 44-50), said valve adapted for positioning adjacent said nostrils of a nose (fig.1); and wherein said valve is adapted to permit air flow through said opening upon a patient breathing in a first direction, and to prevent air flow through said opening upon the patient breathing in a second direction opposite the first direction.

As to claim 32, Baker discloses the integrally molded valve to comprise an exhalation valve (26).

As to claim 35, Baker discloses said mask (12) to comprise translucent material (col.2, lines 44-50).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baker ('671) in view of Benos ('964).

The difference between Baker and claim 34 is the exhalation valve comprising a duckbill valve.

Benos teaches an exhalation valve (25) comprising an exhalation valve comprising a duckbill valve for the purpose of providing a means for exhaling without restraint (page 1, col.2, lines 45-53).

It would have been obvious to modify the exhalation valve of Baker to employ a duckbill valve as mere obvious substitution of one well known type of exhalation valve for another. The duckbill valve of Benos would have provided a valve which is easily removed for cleaning and replacing.

***Allowable Subject Matter***

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5. Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. Claims 36-42 are allowed.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 43-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,988,160. Although the conflicting claims are not identical (all elements of claim 43 are found in patent claim 1-13: an inlet (col.6, lines 21-25); a nosepiece (col.6, line 30); an exhalation valve (col.6, line 40); an extension of instant application claim 43 (col.6, line 47); first and second frustoconical portions (col.6, lines 27 and 28, respectively), they are not patentably distinct from each other because the difference between claim 43 and patent claim 1 lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 1 is in effect a "species" of

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the "generic" invention of claim 43. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 43 is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1.

Claim 43 recites an aerosol inlet which is found in patent claim 2 at (col.6, lines 21-25); the mask comprised of a first and second frustoconical taper which is found in patent claim 2 at (col.6, lines 27 and 28, respectively); a one-way valve recessed in an extension which is found in patent claim 2 at (col.6, lines 40-48).

The difference between claim 43 and patent claim 2 lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 2 is in effect a "species" of the "generic" invention of claim 43. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 43 is anticipated by claim 2 of the patent, it is not patentably distinct from claim 2.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 31-52 have been considered but are moot in view of the new ground(s) of rejection.

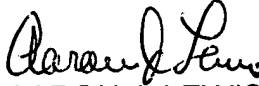
### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant masks having integrally molded valves.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
AARON J. LEWIS  
Primary Examiner  
Art Unit 3743

Aaron J. Lewis  
March 20, 2005